

CHAPTER IV: ACUPUNCTURE: AN EVIDENCE-BASED ASSESSMENT

Does Acupuncture Work?

What I want to do briefly this evening is to answer 2 related questions about acupuncture. Does it work and how does it work? Well, we talk about does it work; we'll say, does it, in fact, work better than placebo? Does it work as well as western medicine? If you compare acupuncture say to steroid injection for tennis elbow, does acupuncture work at least as well as steroid injections and, hopefully, does it have fewer side effects? How do we do acupuncture research? We said that the way we do research is set up for a drug or for surgery. Acupuncture is neither a drug nor a surgery. It is very difficult to fit it into an existing model for how to do research. What's the current state of acupuncture research? When we talk about how it works, I'll briefly talk about how it suppresses pain, how it works differently from the way western medicine works, evidence for these acupuncture points and meridians, and the exciting new directions in which acupuncture is heading.

Before we talk about does acupuncture work, we have to think about what that question means because I think it has very different meanings if you're a patient, if you're the acupuncturist, if you're a physician, or if you're a clinical researcher or basic science researcher. The question has different meanings. If you're a patient, you want to know will it help me, will it improve my health, will it alleviate my symptoms? That's what you mean by does acupuncture work. If you're an acupuncturist, you're saying, will it treat most of my patients for most of their conditions? If you're a physician, what you really want to know is does acupuncture work so I can refer my patients for care? The question, again, has different meanings. If you're a clinical researcher, as we said, it's a more precise definition. If you're a clinical researcher, you ask, is it more effective than a placebo and is it at least as effective as usual care? A basic science researcher asks the questions, how does it achieve its healing effects and is acupuncture working at the molecular and cellular level the way western pharmacology acts? Or can we begin to explain how acupuncture works at another level, in terms of this energy that the Chinese are talking about.

Why I am showing you this? This is one of the ways we can understand that acupuncture is more than a placebo. It turns out that in China, there is as long a history of veterinary acupuncture as people acupuncture, as human acupuncture. In the desert regions of China, there are camels that are used for work, as work animals, and camels get bad backs as do racehorses and cattle. There are many diagrams in veterinary acupuncture books. To me, it's a beginning argument to make that if you can successfully treat a camel, that acupuncture is not acting as a placebo.

But more to the point, no pun intended, this was a study done in 1987 of women who were referred to an acupuncture clinic from the Kaiser Permanente system from the HMO in Oakland for primary dysmenorrhea. As in any kind of research study, what we do is we set up different groups. The women with primary dysmenorrhea were randomly assigned to 4 different groups. One group would get real acupuncture, one group would get sham acupuncture.

What do we mean by sham acupuncture? In this case, they would be given the same number of needles but at points that were not acupuncture points in a way that the women couldn't tell who was getting the real treatment and who was getting the sham treatment. They did 2 more, what we call, control groups. The third group came in and talked to a nurse practitioner about what they were doing for their pain, about their lifestyle, and about whether or not they could make any dietary changes. They got the same amount of attention as the women getting either the acupuncture or the sham acupuncture, and the fourth group got no special treatment. Now, all of the women in the study were not only allowed but they were encouraged to keep taking any pain medication that they needed and, in fact, they kept a diary in which they recorded the amount of pain medication they took each month.

What happened was they got 3 months of acupuncture or sham acupuncture; they came for visits for 3 months. At the end of that period, after the acupuncture treatment, here's what happened. What we are looking at here is the amount of pain. What they simply did

was create a pain scale that was based on the number of days that you were in pain times the amount of pain, the intensity of pain, how painful were your periods. So, at baseline, the amount of pain was reduced after 3 months of acupuncture, very significantly with real acupuncture, and 1 year later, with no further treatments. One year later, the pain was still significantly decreased. In the sham group, the initial level of pain was slightly reduced after the acupuncture treatments and it remained slightly reduced. There were no changes at all in the women who just came to the visits and no changes in the women who had no special treatment.

This is one of the fascinating things about acupuncture; I don't tell my medical colleagues this, but acupuncture appears to remind the body about what it is supposed to be doing. It gives it a physiological nudge and it maintains it. It resets the body. So, instead of taking Advil 1 month and having to take Advil a month later, acupuncture has maintained its health, its new healthy level.

As we said, when we do clinical trials of acupuncture, we ask: is it more effective than no treatment or than a placebo treatment; is it at least as effective as usual care; and can it enhance the effectiveness of usual care? I am going to very briefly show you 3 articles to give you an idea of the breadth of studies that have now been done on acupuncture, that have been published in western medical journals.

Very quickly, here's a study where acupuncture was compared with no treatment and, again, I have chosen a study for women's health. This is effective acupuncture on the duration of labor. Beginning at week 36 of gestation, week 36 of pregnancy, they gave 4 treatments once per week with acupuncture. The comparison group consisted of women who delivered closely before or after the women who were receiving acupuncture. What they found was that the acupuncture group had a significantly shorter time of first stage of labor, which they defined as 3-cm dilation to full dilation. So, 196 minutes is a little over 3 hours; in Group B, without acupuncture, the time was 300 minutes, which is a little over 5 hours. No change in the second stage of labor, full dilation to delivery. So we have a very significant effect of acupuncture here.

In the second study, acupuncture was compared to a beta blocker, to a very commonly prescribed drug for patients with migraine. This was a study done in Sweden. Group A was given acupuncture plus placebo medication. Why? When you get acupuncture, it's commonly a 30-minute treatment. You're lying down, you're very calm and when you're taking pills, you just take pills with a glass of water, finished. So, maybe the effects of acupuncture were due to all the relaxation and not due to the actual treatment. In the study, the group that got acupuncture also got placebo medication, and the group that got the active medication also got sham acupuncture for a 1/2 an hour. They balanced out the attention. After 17 treatments, once a week, the frequency of migraines decreased in both groups. Both the group getting acupuncture and the group getting the beta blocker decreased their number. There was no difference between the groups. In this case, acupuncture was as effective as usual care but markedly fewer side effects were reported—there was much less drowsiness in the acupuncture group than in the group that received the beta blocker.

Finally, here's a study that was done at the University of Maryland, very close to here. The success of this study has now led to the largest study of acupuncture in the country, which is now going on at, again, the University of Maryland for osteoarthritis of the knee. In this early study, all of the patients were allowed to take their normal pain medication and their anti-inflammatory medication, but 1/2 of the people also got acupuncture. They found that for 8 weeks, and at week 4 and week 8, the group receiving acupuncture felt significantly less pain and stiffness and greater physical function than those who only took their medication. They also found no adverse effects of acupuncture.

How do we look at this as a whole, instead of looking at individual studies? In 1997, there was a landmark conference on acupuncture. Up until that time, it was the largest conference that looked at the effectiveness of acupuncture in the west. It was a real coming of age. It was held at the NIH, and they have a mechanism of consensus development conferences, where they look at any emerging new treatments. They've had these kinds of conferences on the importance of trace metals in the diet, on new

heart/lung machines, on early detection of cancer. The NIH felt, in their wisdom in 1997, that acupuncture was emerging medicine. It doesn't matter that it was being used for 2 millennia someplace else in the world, but here the NIH felt it was time to have a very serious look at it. So, the mechanism of this consensus conference is they have 12 wise men, 12 MDs and PhDs sit up on a stage. It's much more like a law trial than it is a scientific conference. They listen to the evidence of acupuncture for all different conditions, and this evidence was only based on published research. They didn't want to hear acupuncturists come up and describe what they did for patients, and they certainly didn't want to hear testimonials from patients who had received acupuncture. The NIH only looks at research.

So, like a law trial, what they did was, after the 2½ days, the panel of 12 people were sequestered in their hotel room. They were told to write their report now, not go home, not call each other, not e-mail, but write the report now. The next morning, we all gathered and this is what they concluded: "Sufficient evidence of acupuncture's value to expand its use into western conventional medicine and to encourage further studies." That means that the NIH should provide more funds for doing research to see how many conditions that it really works for. It wasn't only the NIH and the *Journal of the American Medical Association* who published the full conference report and that were interested; there was widespread interest in this NIH report. This is from an article by Jane Brody, "The panel calls for wider acceptance, says it works for a number of ailments."

What were these ailments? What did the consensus conference really say? They basically came up with an A list and a B list. Their A list was very small. They said, "in terms of the kind of evidence, we're used to accepting for any medical condition, there really are only 2 conditions that we feel the research supports the effectiveness of acupuncture. Nausea that results after operation, when you're recovering from the ether and other anesthetics, and nausea that is related to chemotherapy." They felt that there was good evidence that acupuncture was effective for treating this nausea and even the vomiting that resulted. There was also very good evidence to suggest that acupuncture was useful

for treating postoperative dental pain. But those were the only conditions that made their A list. Their B list, was conditions for which the evidence suggested acupuncture might be useful, that there was some evidence that was suggestive for acupuncture. This was a whole list of conditions that, much more commonly, patients go to an acupuncturist to be treated for.

But now it's 2003, it's 5 years since this NIH consensus conference, and there's been a lot of research that has been done in these past 5 years—a lot of very good research and a lot of research that needs to be examined to look at the quality. What the NIH recommended is very important for insurance companies to decide what to reimburse for, and for physicians to look at to see what they should recommend their patients for, what they should refer to an acupuncturist for. But if the A list was only these few conditions, we felt, in Oregon, the time had come to start looking at the past 5 years.

What we did was we came up with a document, which was a kind of a score sheet, basically. It's called an instrument scientifically or a questionnaire but, basically, we based a score sheet on 2 documents that were already being used. A number of western medical journals, in the early 1990s, got together and said, "look, people are continuing to send us studies to be published on drugs and on surgery and on medical devices. When they do clinical trials, we need some standards for what they report, some commonality, so we know what to look for, what to base our judgments on." They came up with what they called a CONSORT statement, which stands for Consolidated Standards of Reporting Trials. When you write an article, here's what you have to include; they had a 22-item guideline. Well, 2 years ago, the acupuncture community got together, looked at these and decided it was excellent and that we should apply these also to acupuncture. But we basically fine tuned the CONSORT statement, so we had 6 items that were fine tuned to acupuncture—you needed to tell us how many needles you used and what points you needed.

What we did was we took these 2 guidelines, one for the western medical journals and the other for acupuncture journals, and combined them and converted the guidelines into

a 27-question instrument, to a questionnaire. We decided that each question should be scored; a yes was a 2, a partial was a 1, a no was a 0. What did we find? We found, first of all, that in the 5 years since the NIH consensus conference, that there were 105 randomized control trials of acupuncture, which we found in our database. If you add the height of all these bars, it will come out to 105, the total number of trials. This bar graph shows the scores that we gave to all of the articles. We arbitrarily decided that 70% should be a passing grade. In other words, if an article got a score of at least 70%, we said that the article was of reasonably good quality. So, only 32 articles out of 105 scored at least 70%: 20 articles got a score between 70% and 79%; 11 scored between 80% and 89%; and only 1 got a score between 90% and 100%. There's a lot of room for improvement, basically; that's the bottom line that we found in acupuncture research.

Nevertheless, there were 32 studies that got a passing grade. Let's look at these 32 studies. That's this total here and let's look at it in two ways. What were the conditions that were tested on these high-quality studies, what were the conditions? Did the study turn out positive or negative? Did the study show that acupuncture was effective or not? So, of these 32 studies, 2 of them were from the original NIH A list and I'll go over what they were; 23 were the B list conditions; and 7 tested other conditions. Of the B list, 13 out of the 23 were positive, and both A list conditions were positive—a total of 18 out of the 32 came out showing that acupuncture was positive, 14 that showed acupuncture was negative. I'll talk in a minute about these 18.

What do we say about these 14 high-quality studies that suggested acupuncture is not effective? I think that we need to think about acupuncture in the same way we think about pharmacology. If we test a particular drug for a particular condition and it comes out negative, we don't say pharmacology doesn't work. We test a different drug for that condition; we test a different dose of that drug for the same condition. That's what needs to be done in these 14 studies. I believe that there are other sets of other acupuncture points, other conditions for giving acupuncture that now can be tried.

But for now, let's talk about these 18 studies. The 2 from the A list—one, again, an excellent study done at UCLA Medical Center, showing that acupuncture was very effective for controlling the nausea from women who were getting bone marrow transplants for breast cancer, that the antiemetic medication, the medication for controlling the nausea, was not strong enough to fully control the nausea. That's why the human subjects group at UCLA allowed this study to be done, where everybody got the best medication but 1/2 of them also got acupuncture. A positive outcome for acupuncture, and, as I said, these are the 2 on our high-quality list. Another study for postoperative dental pain, so these are the 2 from the A list.

The B list is what's most interesting. They were a range of myofascial pain syndromes. These are all categories that the NIH initially used. So there were 23 additional high-quality studies in areas that the NIH looked at in 1997. For myofascial pain, for shoulder pain, and neck pain in these studies, there were 3 studies, and all 3 were positive. For women's health mainly, I showed you one study, during labor. There were 5 studies, 4 of them were positive. The NIH decided that low back pain should not be included under myofascial pain. Many people think that low back pain can be included in this category, but we'll keep it separate. In any case, there were 3 studies, and 2 were positive. We range down to 3 studies for stroke rehabilitation, none of them positive; 1 headache study, not positive. What do we say about our results?

First, that the NIH A list, after 5 years now, is strengthened for chemotherapy-related nausea and postoperative dental pain. On the basis of our findings, we are going to recommend that both myofascial pain and women's reproductive health, that acupuncture during labor, be added to the A list. We further think that the B list evidence is strengthened, both for low back pain and osteoarthritis; we look at the other conditions, and there isn't enough good evidence to add any additional conditions to the B list. Well, we're now writing this up for publication. We hope that insurance companies will look at this. We hope that physicians will look at the list to see what's happened in the 5 years since that landmark consensus conference in 1997. But, as we said, the importance of this is for insurance companies to look at for possible reimbursement, and for physicians to

look at this list to expand their horizons in terms of what conditions they can refer their patients to for care. But, in addition to this, we want to have a look at the second question that I talked about early in my talk. We asked, does acupuncture work? Now we want to look at how does it work.